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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 01035.0033-01	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____	Application Number 10/764,841		Filed January 26, 2004
	First Named Inventor John F. Boylan		
	Art Unit 3731		Examiner Ryan J. Severson
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>45,284</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p style="text-align: right;"><u>/Louis Troilo/</u> Signature</p> <p style="text-align: right;"><u>Louis Troilo</u> Typed or printed name</p> <p style="text-align: right;"><u>(202) 408-6020</u> Telephone number</p> <p style="text-align: right;"><u>April 30, 2008</u> Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			

☒ *Total of 1 forms are submitted.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)	
)	
John F. BOYLAN et al.)	Group Art Unit: 3731
)	
Application No.: 10/764,841)	Examiner: Ryan J. Severson
)	
Filed: January 26, 2004)	
)	
For: NITINOL ALLOY DESIGN FOR)	Confirmation No.: 9783
SHEATH DEPOLYABLE AND)	
RE-SHEATHABLE VASCULAR)	Mail Stop AF
DEVICES)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

In reply to the final Office Action mailed October 31, 2007, and further to the Notice of Appeal filed herewith, Applicants respectfully request review of the outstanding rejection in view of the following remarks. Claims 1-6 and 15-20 are pending and subject to examination.

I. REJECTIONS UNDER 35 U.S.C. § 103

A. Claims 1, 2, 4, 6 and 15-20

Claims 1, 2, 4, 6 and 15-20 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,910,154 to Tsugita et al. ("Tsugita") in view of U.S. Patent No. 5,885,381 to Mitose et al. Office Action at pp. 2-3. The Examiner asserts that Tsugita "discloses the invention substantially as claimed, including a 'self-expanding strut assembly' (54) including a nickel-titanium alloy'" (citing col. 8, lines 48-50) and "a 'filter element' (60) disposed on the strut assembly'" (citing Figures 6A and 6B). *Id.* at p. 2. However, the Examiner admits that Tsugita "does not disclose the superelastic alloy includes a ternary element." *Id.* To remedy this deficiency, the Examiner relies on Mitose. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to replace the nickel-titanium strut assembly of Tsugita reference with the alloy of Mitose having a ternary

element (palladium) to reduce the stress hysteresis and improve hot workability in the device. *Id.*

Applicants respectfully disagree and traverse this rejection for at least the following reasons.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. In *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q. 2d 1385 (2007), the Supreme Court confirmed that the “framework for applying the statutory language of §103” was still based on its landmark decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). As detailed below, it is evident that the Examiner has not established a *prima facie* case of obviousness even in light of the *KSR* decision. Specifically, the Examiner has failed to show that the alloys disclosed in the cited references exhibits a decreased stress hysteresis **due to a lowered loading plateau stress**, as claimed. In fact the Examiner cannot show this because the references, namely Mitose, desire just the opposite.

Hysteresis is defined by the difference between the loading and unloading plateau stresses of the material as plotted on a stress-strain curve. To illustrate the difference of the present invention in comparison with Mitose, as discussed above, Applicants submit the following three figures. Figure 1 represents a typical stress-strain hysteresis. Figure 2 represents the mechanism by which Mitose achieves a smaller hysteresis. As discussed in Mitose at col. 5, lines 25-28, and as indicated by the upward arrow, a smaller hysteresis is a result of a higher unloading plateau stress. Figure 3 is an illustrative superelastic stress-strain curve according to the present invention in comparison with the standard superelastic NiTi. This Figure shows a downward arrow indicating a smaller hysteresis is a result of a lower loading plateau stress.

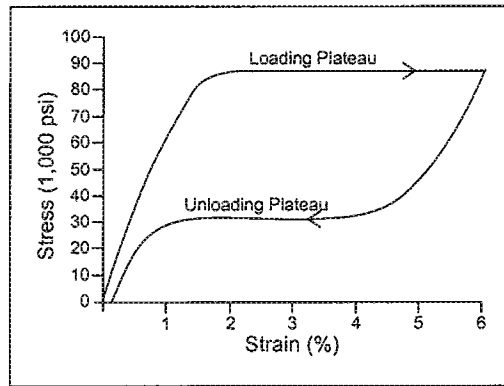


Figure 1: Typical Stress-Strain curve for superelastic NiTi.

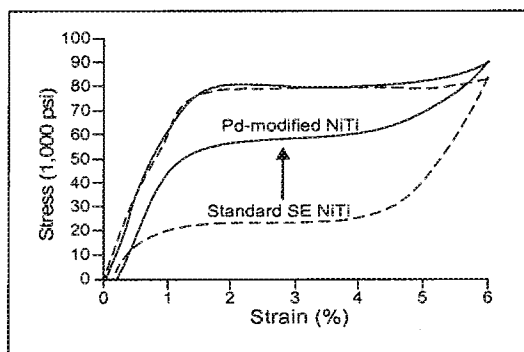


Figure 2: Superelastic stress-strain curve described in Mitose.

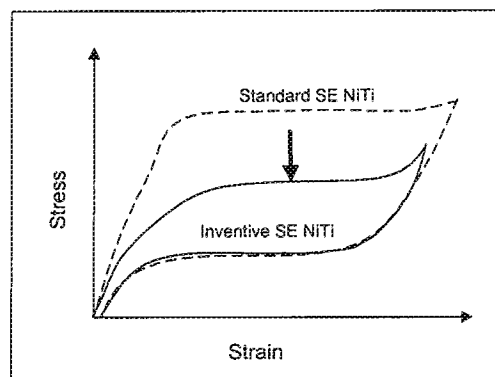


Figure 3: Illustrative superelastic stress-strain curve according to the present invention.

The graphical representation mentioned above is not only taught in Mitose, but it is specifically exemplified. As shown, in col. 7, lines 35-40, the inventive alloys of Mitose (1-8) achieved desired properties over the closest comparative examples 9 and 10, which contain Pd, like Examples 1-8, by increasing the unloading stress.

Thus, even if the intent of Mitose (to achieve a lower stress hysteresis by adding a ternary element) is the same as the claimed invention, the means by which it is achieved is completely opposite to the claimed invention. Therefore, the Examiner has failed to show that the alloy of Tsugita, alone or in view of Mitose, achieves a decreased stress hysteresis by decreasing the loading plateau stress, as claimed.

The Examiner relies on Figs. 2 and 4 of Mitose to allegedly show that “the plateau stress is lower in the alloy having the ternary element (well below 400 MPa) than the alloy without the ternary element

(at or above 400 MPa).” *Id.* at 5. This comparison is improper for at least the reason that Figs. 1-3 of Mitose represent “prior art” and not comparative examples conducted by Mitose. As such, the figures do not support the Examiner’s conclusion that “the reduction of the stress hysteresis as taught by Mitose . . . is at least in part due to the reduction in the loading plateau.” *Id.* The Examiner is simply comparing apples and oranges.

Furthermore, contrary to the Examiner’s positions, to the extent that Mitose ever explicitly describes the intent of the loading and unloading stress in his inventive alloys, it is to achieve as high of a loading stress as possible. *See, e.g.*, col. 5, lines 22-32 (“[w]hen the superelastic alloy material is used for the orthodontic archwire, it is desired that a certain amount of tensile force should be applied in working (**loading**) to attach the wire to the teeth, and that a tensile force **should be as high as possible** in unloading to move the teeth after attaching the wire to the teeth, namely, the stress hysteresis should be small.”). (Emphasis added) *See also*, col. 10, lines 1-7.

In order to satisfy the initial burden of establishing a *prima facie* case of obviousness, the Examiner first must show that the prior art references teach or suggest all the claim limitations. *See In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). The Examiner must also show that there is some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

Nothing in either Tsugita or Mitose teaches obtaining a decreased stress hysteresis by decreasing the loading plateau stress, as claimed. In fact, this rejection is fatally flawed since it relies on a reference, Mitose, that clearly teaches away from the claimed invention. *See In re Laskowski*, 10 USPQ 2d 1397 (Fed. Cir. 1989). For this reason alone, Applicants respectfully request this rejection be withdrawn.

Additionally, even if the Examiner has established that the claimed invention is obvious, which he has not, an Applicant can rebut a *prima facie* case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. *See* M.P.E.P. § 716.02(a). Accordingly, in order to advance prosecution,

Applicants submitted an article with the Reply filed August 15, 2007, titled, "The Development of Radiopaque Nitinol," written by John F. Boylan ("the Boylan article"), one of the inventors of the present application. This document is available in the Image File Wrapper (IFW). Applicants submit that this article provides evidence that establishes that the claimed embolic filter system comprising a strut assembly which includes a nickel-titanium alloy and a ternary element, as recited in claim 1 for example, is unexpectedly superior as compared with the Nitinol struts disclosed in Tsugita.

For at least the foregoing reasons, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness over on Tsugita and Mitose. Moreover, even if the Examiner has established that the claimed invention is obvious, Applicants have presented sufficient evidence to rebut any *prima facie* showing. Accordingly, Applicants respectfully request that this rejection be withdrawn.

B. Claims 3 and 5

Claims 3 and 5 are rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Tsugita in view of Mitose and further in view of U.S. Patent No. 5,713,853 to Clark et al. ("Clark"). Office Action at p. 4. Applicants respectfully disagree and traverse this rejection for at least the following reasons.

As discussed above, the Examiner has failed to show that Tsugita or Mitose provide any reason why one of ordinary skill in the art would have combined the elements in the manner claimed. Clark does not remedy the deficiencies of Tsugita and Mitose. In fact, because Clark is not concerned with superelastic materials it never mentions a stress hysteresis, and certainly does not teach how to reduce a stress hysteresis, as claimed. Thus, this combination of references does not establish a *prima facie* case of obviousness of claims 3 and 5. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

/Louis Troilo/

Dated: April 30, 2008

By: _____
Louis M. Troilo
Reg. No. 45,284